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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/963,777 | 09/26/2001 | Robert S. Kieval | 1151.1106101 | 1758 |
| 20350 | 7590 | 09/13/2005 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | OROEZA, FRANCES P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Tln

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/963,777 | KIEVAL ET AL. | |
| | Examiner | Art Unit | |
| | Frances P. Oropeza | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/23/05 (Response).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,10,12,14,22,24,26,33,34,37,38,44 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6-9,11,13,15-21,23,25,27-32,35,36,39-43,45 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>9/1/05</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Response

1. The Applicant's arguments filed 5/23/05 are convincing hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 6-9, 15-21, 27-32 and 39-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Zabara (US 5540734) and Bullara (US 4573481).

Zabara teach an apparatus / method for stimulating the carotid sinus (15) using a helical electrode array (US 4573481 to Bullara, incorporated by reference col.7 @ 18-20). The electrode is placed on/ proximate the carotid sinus, the extent of electrode placement determined by the surgeon (figure 2; col. 4 @ 45-65; col. 7 @ 18-20 and 46-48). Based on the figure 1 in Bullara, the base of the two or more electrodes are wrapped in a circular manner such as not to damage the blood vessels (col. 2 @ 26-29), per Zabara the extent of the wrapping (i.e. to include the internal, external and common arteries; a portion or the totality of the carotid sinus; a joining of the electrode ends) determined by the surgeon based on the patient and the application.

As to the application of the device as an inducer of a baroreflex, this limitation is read as intended use which Zabara performs or is capable of performing.

Claim Rejections - 35 USC § 103

4. Claims 11, 13, 23, 25, 35, 36, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zabara (US 5540734) and Bullara (US 4573481) in view of Schwartz et al. (US3522811).

As discussed in paragraph 3 of this action, Zabara discloses the claimed invention except for the activation device having a base and a plurality of electrodes mounted parallel to the base, the activation device mounted orthogonal to the nerve.

Schwartz et al. teaches nerve stimulation using the activation device having a base and a plurality of electrodes mounted parallel to the base, the activation device mounted orthogonal to the nerve for the purpose of stimulating to carotid nerve. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the activation device having a base and a plurality of electrodes mounted parallel to the base, the activation device mounted orthogonal to the nerve in the Zabara system to provide an alternate proven electrode configuration that has suitability in specific applications based on the extent of the disease and anatomical configuration of the patient (figure 1).

5. Claim 47 is over Zabara (US 5540734) and Bullara (US 4573481) in view of Kieval (US 6178349).

As discussed in paragraph 3 of this action, Zabara discloses the claimed invention except for the electrodes being sutured.

Kieval teaches electrode stabilization using sutures for the purpose of securing the electrode in its anatomical location. It would have been obvious to one having ordinary skill in

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the art at the time of the invention to have used a suture in the Zabara system in order provide means to ensure the activation device remains in the proper location so patient treatment can be given efficiently and effectively, avoiding the risk ad expense of future surgery to correct a misplaced neural stimulation electrode (col. 5 @ 55-58).

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

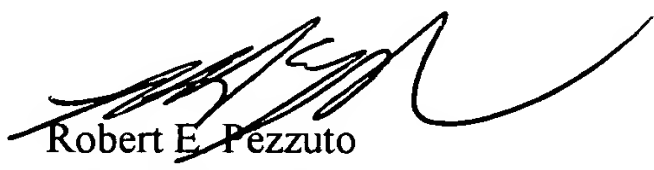
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
9/7/05


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3762